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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,498	08/14/2006	Colin G. Caro	DEHN 200008US01	7739
27885	7590	02/17/2010		
FAY SHARPE LLP 1228 Euclid Avenue, 5th Floor The Halle Building Cleveland, OH 44115			EXAMINER WOLF, MEGAN YARNALL	
			ART UNIT	PAPER NUMBER
			3738	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,498	<b>Applicant(s)</b> CARO ET AL.	
	<b>Examiner</b> Megan Wolf	<b>Art Unit</b> 3738	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,8,9,12,13 and 28-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,8,9,12,13 and 28-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Response to Arguments***

1. Applicant's arguments filed 10/30/09 have been fully considered.

Arguments regarding the rejection of claims under 35 U.S.C 102(e) as being anticipated by Cymbalisty are persuasive in view of the amendments to the claims. Arguments regarding the rejection of claims under 35 U.S.C. 103(a) as being unpatentable over Caro in view of Cymbalisty have been considered but they are not persuasive. In response to applicant's argument that Cymbalisty is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Cymbalisty is reasonably pertinent to the particular problem with which the applicant was concerned, specifically, inducing swirl flow in a tube. Applicant argues that one of ordinary skill in the art of grafts would not look to Cymbalisty for useful teachings since Cymbalisty is directed to static mixing of slurries. The examiner disagrees. While the examiner appreciates that there are differences between Cymbalisty and the art of grafts, they share the common objective of producing swirl flow within a tubular lumen. Caro discloses a tubular graft that is helically shaped to induce swirl flow to improve circulation and resist the formation of potentially damaging blockages within the interior (col.3, ll.50-55). Cymbalisty, teaches a specific helical shape, including a helix angle and line of sight through the tube

Art Unit: 3738

which is identical to that claimed, for the purpose of inducing swirl flow of the medium flowing through the tube (col.2, ll.39-47). Therefore, the examiner maintains that since Caro strives to create swirl flow within the tubular graft, and Cymbalisty teaches a specific helical orientation for the purpose of creating swirl flow, it would have been obvious to one of ordinary skill in the art to combine the two references.

2. Arguments on page 11 regarding pulsating flow are not persuasive. The claims are not specifically directed to use in the vascular system. The claims include graft use in carrying “other bodily fluids”, which would not necessarily be subjected to pulsating flow.

3. Applicant also argues that mixing is not an issue in an in vivo graft as it is in Cymbalisty, but applicant's specification paragraph 16 specifically discusses that swirl flow is beneficial because it creates “mixing over the cross section” of the graft to reduce the potential for deposit build up within and downstream of the graft. As such, Cymbalisty may be relied upon as a basis for the rejection since the reference is directed to mixing material within a tubular structure.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

Art Unit: 3738

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-3, 8, 9, 12, 13, 28-31, and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/549211. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims only differ in terminology and intended use. The claims in both applications includes a tubular portion substantially free of ribs or grooves, wherein the center line of the lumen follows a helical path with a helix angle less than or equal to 15° and the amplitude of the helix is less than or equal to one half of the internal diameter of the tubing portion. The dependent claims are identical aside from the preamble which includes intended use of the product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3738

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 8, 9, 12, 28-30, 32-34, 37, and 38, are rejected under 35

U.S.C. 103(a) as being unpatentable over Caro 6,039,754 in view of Cymbalisty 6,896,007.

Re claims 1-3, 8, 28, and 37, Caro discloses the invention substantially as claimed including a graft capable of use in vivo to carry blood or other bodily fluids comprising flow tubing having a tubing portion defining a flow lumen, the flow lumen being substantially free of ribs or grooves, wherein the graft is set such that the center line of the flow lumen follows a substantially helical path (col.3, ll.50-55). However, Caro does not disclose that the centerline of the flow lumen has a helix angle of less than or equal to  $45^\circ$  and the amplitude of the helix is less than or equal to one half of the internal diameter of the tubing portion wherein the amplitude of the helical center line divided by the internal diameter of the tubing is a least 5%.

Cymbalisty teaches flow tubing, in the analogous art of conduits, wherein the tubing is set such that the center line of the flow lumen follows a substantially helical path with a helix angle of  $11.3^\circ$  (helix angle =  $\tan^{-1}(D/P) = 11.3^\circ$ ; see fig.3 where  $P=5D$ ) and an amplitude of the helix less than or equal to one half of the internal diameter of the tubing portion wherein the amplitude of the helical center line divided by the internal diameter of the tubing is a least 5% for the purpose of

Art Unit: 3738

creating dynamic mixing and swirl flow of its contents (col.2, ll.41-44) which prevents deposition of solids within the tube (col.4, ll.1-2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the generic helical formation of the graft of Caro in view of the specific dimensions taught by Cymbalisty in order to provide flow tubing that creates swirl flow and prevents blockages with the interior of the graft. The open channel shown in Cymbalisty is also effective to help provide a conduit for blood even if blockages do form along the tubing walls.

Re claims 9 and 29, the cross section of the tubing of both Caro and Cymbalisty is substantially circular (figs. 5 and 2 respectively).

Re claims 12 and 30, see Caro fig.6.

Re claims 32 and 33, see Caro col.3, ll.58-61.

Re claims 34 and 38, Caro teaches that the graft is formed of known suitable biocompatible material (col.3, ll.55-58) and that the graft maintains its shape prior to implantation (clm.1). The process by which the device is made, including thermosetting, is not germane to the issue of patentability of the device itself (see MPEP 2113).

8. Claims 13 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro 6,039,754 in view of Cymbalisty 6,896,007 as applied to claims 1 and 3 above, and further in view of Healy et al. 5,670,161. Caro in view of Cymbalisty discloses the invention substantially as claimed, but does not disclose a graft comprising a pharmaceutical coating.

Art Unit: 3738

Healy discloses a stent graft, in the same field of endeavor, comprising a drug coating for the purpose of positively affecting healing at the site of implantation (col.10, ll.10-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add a pharmaceutical coating to the graft of Caro in view of Cymbalisty in order to induce healing at the site of implantation, as taught by Healy, col.10, ll.10-13. It is well known in the art to coat a graft with pharmaceuticals to prevent thrombosis, etc.

9. Claims 35, 36, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro 6,039,754 in view of Cymbalisty 6,896,007 as applied to claims 1 and 37 above, and further in view of Angelini GB 2298577 (submitted in IDS). Caro in view of Cymbalisty discloses the invention substantially as claimed and as discussed above. Caro further discloses that in order to maintain the tubing open a stent or other structural support may be used internally, externally, or integral with the wall of the tubing (col.3, ll.58-61). However, Caro in view of Cymbalisty does not specifically disclose that the external support may be in the form of a helical winding wherein the helix angle of the helical winding is larger than the helix angle of the helical center line of the flow lumen.

Angelini teaches a graft, in the same field of endeavor, wherein a stent with a large helical angle (as discussed in the current application par.69) is used around a graft for the purpose of providing beneficial effects on the luminal size, the degree of medial and intimal thickening, and cell proliferation (pg.2, ll.11-15).



Art Unit: 3738

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the graft of Caro in view of Cymbalisky to include the external helical winding taught by Angelini in order to help maintain the circular cross-section of the tubing. As Angelini discloses a helix angle of the helical winding to be close to 90°, the helix angle of the helical winding is larger than the helix angle of the helical center line of the flow lumen of the device as modified.

### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

Art Unit: 3738

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./

Examiner, Art Unit 3738

/David H Willse/

Primary Examiner, Art Unit 3738